Sisters of Saint Joseph
Mount Saint Joseph Convent
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November 20, 2002

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061, (HFA-305)
Rockville, MD 20852.

Dear FDA:

Docket No. 02D-0325

We, the Sisters of Saint Joseph, Philadelphia, as faith based investors and members of the Interfaith Center on Corporate Responsibility (ICCR), write in response to the draft guidance document recently released for comment by your agency. Members of ICCR have been addressing health-related companies since 1998 asking them to phase out the use of PVC and DEHP in medical products. Therefore we join other ICCR members in urging you to support your own Public Health Notification on the plasticizer di-(2-ethylhexyl) phthalate (DEHP) in medical devices, with policies that will enable providers to implement its recommendations. In particular, we urge the FDA to require labeling of medical devices containing DEHP.

The Public Health Notification issued by your agency last summer, identified a number of medical procedures that posed the highest patient risk from DEHP exposure, including enteral nutrition, infants receiving parenteral nutrition and exchange transfusions. In September, a draft guidance document was issued which recommends that medical device manufacturers help minimize patient exposure to DEHP by clearly indicating "through user labeling" devices that contain DEHP, and by "replacing PVC containing DEHP" with alternative materials.

This voluntary approach does not provide assurance that devices will be labeled, nor that practitioners will have enough information to make informed decisions. If manufacturers choose not to label their DEHP-containing products, medical device users would be left in the dangerous position of not knowing whether or not they were using a DEHP-containing product, making protection of vulnerable patients very difficult. Furthermore, obtaining information from manufacturers as to whether or not a product contains DEHP is not always an easy task.

We urge the FDA to formulate policies that allow practitioners to implement the Public Health Notification issued by your agency. Without labeling, it is difficult to understand how practitioners are to carry out the FDA recommendations. We urge the FDA to give them the tools they need to protect the health of patients.

Thank you for your consideration of this important concern.

Sincerely,

Kathleen Coll, SSJ

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Social Justice Coordinator

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Cc: Mary Ellen Gondeck, SSJ, Donna Meyer, Ph.D., Co-Chairs, International Health and Tobacco Steering Committee, Interfaith Center on Corporate Responsibility